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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/913,811	09/24/1997	HIROKAZU SUGIHARA	356972020100	7552

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/21/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/913,811

Applicant(s)

SUGIHARA ET AL.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 1645

**DETAILED ACTION**

1. Applicant's response filed on 1/29/02 (Paper # 30) is acknowledged. Claims 12, 14 and 16 are pending in the application.
2. In view of applicant's arguments filed on 1/29/02, all the rejections of record are withdrawn.

**Double Patenting**

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 12, 14 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No.6, 297,025. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed method of testing the chronic effect on neuronal muscle tissue samples of chemical substance using a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample and detecting an electrical property of said tissue before and after adding the chemical substance is an obvious variation upon the patented claims which are drawn to a method for observing electrical waveforms in a tissue slice comprising plurality of microelectrodes on a substrate for contacting the tissue sample and detecting an electrical property of said tissue before and after adding the chemical substance.

Art Unit: 1645

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12, 14 and 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rejected as being vague and not clear. The claim is confusing since the device (i.e., detector comprising) in lines 5-6 is mixed with the method (i.e., contacting, detecting) steps. Applicant is advised to amend the claim to recite the device and method steps separately.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al 1982 (Brain Research, 244: 382-386).

Yamamoto et al disclose a method of testing the effect of black widow spider venom (chemical substance) providing contacting the hippocampal tissue sections with glass micropipettes filled with potassium acetate for measuring intracellular potentials (see abstract and page 382). Electrical stimulation was given to the tissue sample (i.e., electrodes on a substrate) and electrical properties were measured before and after the addition of venom (figures 1 and 2). Further, the synaptic transmission after prolonged administration (3 days) of

Art Unit: 1645

venom (page 385, left column first paragraph through right column) is also disclosed. The prior art anticipated the claimed invention.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Gross et al. (J. of Neuroscience Methods 5: 13-22, 1982).

Gahwiler et al 1982, teach a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after addition of said substances (see results and figures). Although the prior art used standard

Art Unit: 1645

electrophysiological techniques for recording the electrical properties, the prior art specifically does not teach providing a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample (i.e., the device or apparatus).

Gross et al teach an apparatus (see material and methods/figures) for observing a physical and chemical property of a tissue or cells comprising providing photoetched electrodes integrated into the floor of a tissue culture chamber (i.e. providing a substrate with planar electrodes disposed on the same plane as the substrate) and a cell culturing means. (page 13). Gross et al teach recording the electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of neuronal activity. It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to use the apparatus designed by Gross in a method of Gahwiler et al to measure the electrical properties before and after addition of chemical substances because Gross et al suggests that the apparatus disclosed is obviously designed for long term cultures. The motivation to use this apparatus to achieve the obvious benefits is clearly suggested by Gross (see page 21, last paragraph). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the apparatus as taught by Gross et al for measuring and comparing waveforms or electrical properties of neural tissue before and after the addition of chemical substances as taught Gahwiler et al because the apparatus is designed to measure the effect of different concentrations of the chemical substances on tissue and comparing the electrical properties of long term cultures.

10. Claims 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Gaiver et al 1993 (U.S. Patent 5,187,096)

Gahwiler et al 1982 teach a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after addition of said substances (see results and figures). Although the prior art used the standard electrophysiological techniques for recording the electrical properties, the prior art specifically does not teach providing a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample (i.e., the device or apparatus).

Gaiver et al teach an apparatus (see claims) for observing a physical and chemical property of a tissue or cells comprising plurality of electrodes integrated into the floor of a tissue culture chamber (i.e. providing a substrate with planar electrodes disposed on the same plane as the substrate) and cell culturing (column 2, Summary of the invention) means. Gaiver et al teach by using this apparatus, the activities of cultured cells that are attached to the surfaces could be followed continuously in real time. The recording of extracellular electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of cell activity to changes in the physical environment and drugs (column 3 and 4). It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to use the apparatus designed by Gaiver et al in a method of Gahwiler et al to measure the electrical properties before and after the addition of chemical substances because Gaiver et al suggests that this apparatus is obviously designed for long term cultures. The motivation to use this apparatus to achieve the obvious benefits is clearly suggested by Gaiver et al (see column 3, lines 23-55). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the apparatus as taught by Gaiver et al for measuring and comparing waveforms or electrical properties of neural tissue before and after the addition of chemical substances as taught by Gahwiler et al because

Art Unit: 1645

the apparatus designed by Gaiver is for measuring the effect of different concentrations of the chemical substances on tissue and comparing the electrical properties of long term cultures.

11. Claims 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Sugihara et al 1995, (EPA: 689051).

Applicant states (see Paper # 22, filed on 4/5/01) that the current application was filed on 9/24/1997. This application is a PCT 371 filed on 1/24/1997, which in turn has priority to Japanese application filed on 1/24/96. The current application also claims priority to U.S. application 08/662,629, filed on 6/13/96, which in turn, is a CIP of 08/464,116 filed on 6/5/1995. Examiner has reviewed the application 08/464,116 filed on 6/5/1995 and found no support for the claimed invention, directed to a method of testing the chronic effect on neuronal muscle tissue samples of chemical substance using a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample and detecting an electrical property of said tissue before and after adding the chemical substance. Therefore, this application does not get priority to 08/464,116 filed on 6/5/1995 and gets priority to U.S. application 08/662,629 filed on 6/13/96. Since this application filed under 35U.S.C 119 (a)- (d), the priority date for the pending claims is 1/24/96. Therefore, Sugihara et al EPA 689051 (12/27/1995) is considered as a prior art.

Gahwiler et al 1982 teach a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after the addition of said substances (see results and figures). Although the prior art used standard electrophysiological techniques for recording, the prior art specifically does not teach providing a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample (i.e., the device or apparatus).

Sugihara et al teach an apparatus for observing physical and chemical property of a tissue or cells comprising plurality electrodes integrated into the floor of a tissue culture chamber (i.e. providing a substrate with planar electrodes disposed on the same plane as the substrate) and a cell culturing means. (Claims). Sugihara et al teach by using the disclosed apparatus, the activities of cultured cells that are attached to the surface could be followed continuously in real



Art Unit: 1645

time. The recording of extracellular electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of cell activity to changes in the physical environment and drugs (claims and figures). It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to use the apparatus designed by Sugihara et al in a method of Gahwiler et al to measure the electrical properties before and after the addition of chemical substances because Sugihara et al suggests that this apparatus is obviously designed for long term cultures. The motivation to use this apparatus to achieve the obvious benefits is clearly suggested by Sugihara et al (see columns 11-12).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the apparatus as taught by Sugihara et al for measuring and comparing waveforms or electrical properties of neural tissue before and after the addition of chemical substances as taught Gahwiler et al because the apparatus designed by Sugihara et al is for measuring the effect of different concentrations of chemical substances on tissue and comparing the electrical properties of long term cultures.

#### ***Status of Claims***

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 08/913,811

Page 9

Art Unit: 1645

Padma Baskar Ph.D.

5/12/02

A handwritten signature in black ink, appearing to be 'P. Baskar', written over the date.

275  
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